SNI

Standar Nasional Indonesia

SNI EN 455-1:2000
(Ditetapkan oleh BSN tahun 2020)

Sarung tangan medis sekali pakai - Bagian 1: Persyaratan dan pengujian bebas lubang

Medical gloves for single use - Part 1: Requirements and testing for freedom from holes

(EN 455-1:2000, IDT, Eng)

SNI ini merupakan adopsi identik dari EN 455-1:2000 dan telah mendapat izin adopsi dari CEN, Rue de la Science 23 B – 1040 Brussel, Belgium

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ICS 13.340

BSN BADAN STANDARDISASI NASIONAL

BSN
Email: dokinfo@bsn.go.id
www.bsn.go.id

Diterbitkan di Jakarta

Daftar isi

Prakata

Standar Nasional Indonesia (SNI) EN 455-1:2000, dengan judul *Sarung tangan medis sekali pakai - Bagian 1: Persyaratan dan pengujian bebas lubang (EN 455-1:2000, IDT, Eng)*, merupakan hasil adopsi identik dari standar EN 455-1:2000 *Medical gloves for single use - Part 1: Requirements and testing for freedom from holes*, dengan metode republikasi *reprint*, yang ditetapkan oleh BSN pada tahun 2020.

Standar ini disusun oleh Komite Teknis 13-09 Biosafety and Biosecurity dengan Badan Standardisasi Nasional (BSN) sebagai sekretariat Komite Teknis. Standar ini telah dibahas dalam rapat-rapat teknis, dan terakhir disepakati dalam rapat konsensus di Jakarta pada tanggal 17 April 2020 yang dihadiri oleh para pemangku kepentingan (*stakeholder*) terkait, yaitu perwakilan dari produsen, konsumen, pakar dan pemerintah, serta perwakilan dari lembaga penguji, asosiasi, perguruan tinggi, pakar serta instansi terkait.

Standar ini telah melalui tahap jajak pendapat pada tanggal 11 Mei 2020 sampai dengan 30 Mei 2020 dengan hasil akhir disetujui menjadi SNI.

Dalam standar ini digunakan kosa kata yang mempunyai maksud tertentu, yaitu:

- “harus” yang artinya disyaratkan.
- “sebaiknya” yang artinya direkomendasikan.

Perlu diperhatikan bahwa kemungkinan beberapa unsur dari dokumen standar ini dapat berupa hak paten. Badan Standardisasi Nasional tidak bertanggungjawab untuk pengidentifikasian salah satu atau seluruh hak paten yang ada.

Sarung tangan medis sekali pakai - Bagian 1: Persyaratan dan pengujian bebas lubang

1 Scope

This part of this Standard specifies requirements and gives the test method for medical gloves for single use in order to determine freedom from holes.

NOTE Attention is drawn to EN 374-1 "Protective gloves against chemicals and micro-organisms – Part 1: Terminology and performance requirements".

2 Normative reference

This Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

ISO 2859-1, *Sampling procedures for inspection by attributes - Part 1: Sampling plans indexed by acceptable quality level (AQL) for lot-by-lot inspection*.

3 Term and definition

For the purposes of this standard the following term and definition apply:

3.1
medical gloves for single use
gloves intended for use in the medical field to protect patient and user from cross-contamination.

4 Requirement

Medical gloves for single use shall not leak when tested in accordance with clause 5.

5 Watertightness test for detection of holes

5.1 Referee testing

Vertically position a filling tube of dimensions shown in figure 1 or of dimensions to fit the glove and such that the tube is capable of holding any of the 1000 ml of water that may exceed the natural fill volume of the glove.

Attach the glove to the filling tube, overlapping the cuff by a maximum of 40 mm over the end of the tube and secure it by suitable means to obtain a watertight seal without damaging the glove (see figure 1).

Add 1000 ml ± 50 ml of water at a temperature of (15 to 35) °C into the open end of the filling tube, allowing the water to pass freely into the glove.

NOTE Some of the water may remain in the filling tube depending on the glove being tested.

Immediately inspect the glove visually for water leakage. Allow the glove to hang and visually inspect the glove for water leakage again after a period of 2 min to 3 min.

If, because of distension of the glove, the water does not rise to within 40 mm of the cuff end, raise the glove after the second inspection by a suitable means until the water level reaches 40 mm from the cuff end. Inspect visually the previously untested portion of the glove after a further period of 2 min to 3 min.

Disregard leakages within 40 mm of the cuff.

5.2 Routine testing

Routine testing shall be either by the watertightness test given in 5.1 or by another test which is validated against this test.

6 Sampling, inspection level and AQL

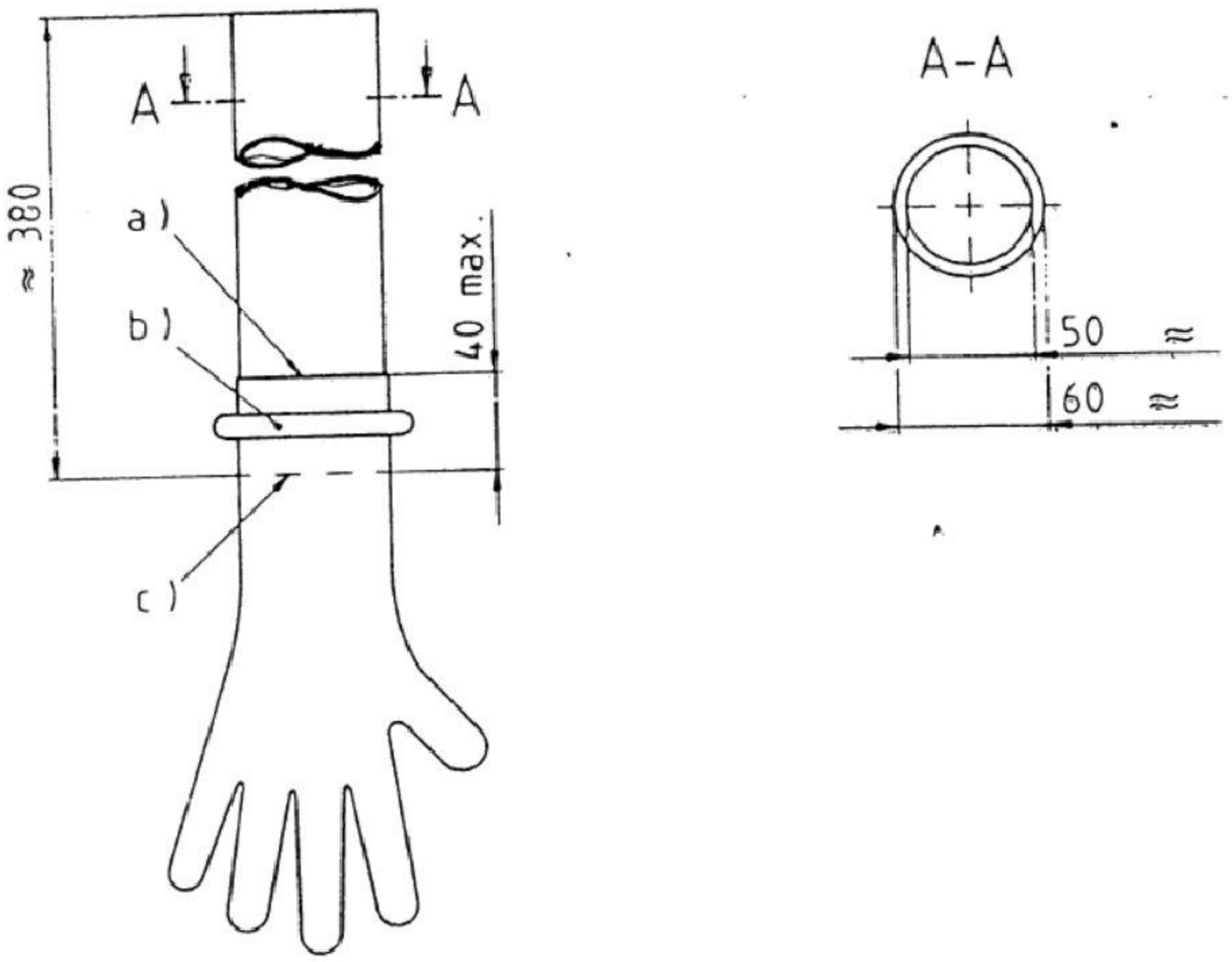
Each lot shall be sampled in accordance with ISO 2859-1 general inspection level 1, but utilising a minimum sample size and corresponding acceptance/rejection numbers equivalent to sample size code letter L. When tested by the method described in 5.1 for referee purpose, the compliance level for freedom from holes shall be an AQL of 1,5.

NOTE This inspection level meets the requirements of Annex IV point 6.3 of the Medical Devices Directive, 93/42/EEC, and does not entail excessive sample sizes which would impact on manufacturing and testing costs. A minimum sample size equivalent to sample size code letter L is necessary to ensure that an adequate assessment of the quality of the lot is obtained when the lot size is small or unknown.

7 Test report

Any test report shall include at least the following information:
– a reference to this part of EN 455;
– the type of gloves and manufacturing batch code;
– the name and address of the manufacturer or distributor and test laboratory, if different;
– the date of the test performed;
– the test results (batch size, sample size, number of non-conforming gloves).

Dimensions in millimeters



Key
a) Cuff end of glove
b) Locking device
c) Fill tube overlapping

Figure 1 - Watertightness test - Filling tube

Annex ZA
(informative)
Clauses of this European Standard addressing essential requirements or other provisions of EU Directives

This standard has been prepared under a mandate given to CEN/CENELEC by the European commission and the European Free Trade Association and supports essential requirements of EU Directive 93/42/EEC.

WARNING Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

The following clauses of this standard, as detailed in table ZA.1, are likely to support requirements of Directive 93/42/EEC.

Compliance with the clauses of this standard provides one means of conforming with the specific essential requirements of the Directive concerned and associated EFTA regulations.

Table ZA.1 - Correspondence between this Standard and EU Directives

Clause/sub-clause of this Standard	Corresponding essential requirement of Directive 93/42/EEC	Comments
4	1, 2, 3, 7.2, 8.1	
5	1, 2, 3, 7.2	
5.2	8.1	
6	1, 2, 7.2, 8.1	
7	1, 2, 8.1	

Informasi pendukung terkait perumus standar

[1] KomiteTeknis
Komite Teknis 13-09 Biosafety and Biosecurity

[2] Susunan Keanggotaan KomiteTeknis

Ketua	:	Sunarya	- The Spring Institute
Sekretaris	:	Agus Purnawarman	- Badan Standardisasi Nasional
Anggota	:	1. Diah Iskandriati	- Pusat Studi Satwa Primata, Lembaga Penelitian dan Pengabdian kepada Masyarakat, IPB University
	:	2. Syafril Daulay	- Komisi Ahli, Badan Karantina Pertanian Kementerian Pertanian
	:	3. Ni Ketut Susilarini	- Pusat Penelitian dan Pengembangan Biomedis dan Teknologi Dasar Kesehatan, Badan Litbangkes, Kementerian Kesehatan
	:	4. Indrawati Sendow	- Balai Besar Penelitian Veteriner
	:	5. Lilyana Budihardjo	- PT.Gaia Science Indonesia
	:	6. Rika R.Sjoekri	- CV.Noesis
	:	7. Arnold Sudharyanto	- PT.Trisakti Mekarmandiri
	:	8. Wanny Basuki	- World BioHazTech Pte. Ltd.
	:	9. Ni Made Ria Isriyanthi	- Subdit Pengawasan Obat Hewan, Direktorat Kesehatan Hewan Direktorat Peternakan dan Kesehatan Hewan. Kementerian Pertanian
	:	10. Aroem Naroeni	- Pusat Riset Virologi (PRVKP), Fakultas Kedokteran Universitas Indonesia
	:	11. Nuryani Zainuddin	- Balai Besar Karantina Pertanian Soekarno Hatta, Badan Karantina Pertanian, Kementerian Pertanian

[3] Konseptor
Gugus Kerja Komtek 13-09

[4] Sekretariat Pengelola KomiteTeknis
Direktorat Pengembangan Standar Agro, Kimia, Kesehatan dan Halal
Badan Standardisasi Nasional